K093901/S004

Section 5: 510(k) Summary

SEP 10 2010

1. **Original Preparation Date:** December 17, 2009

2. **Submitted by:** Epard Protective Products, Ltd.
No. 1 Bailongguan
Quijialing District Jinshan
Hubei, China 431821

Contact Person/Prepared by:

Darren Reeves
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3. **Device Identification:**

Trade Name: Surgical Face Mask
Common Name: Mask, Surgical
Classification: Surgical Apparel (21 CFR 878.4040, Product Code FXX)

4. **Predicate Device:** Tucker & Associates, Surgical Face Mask (K022256)

5. **Device Description:**

Surgical Face Mask ear loop yellow, Surgical Face Mask ear loop blue, Surgical Face Mask tie-on yellow, and Surgical Face Mask tie-on blue

6. **Intended Use:**

This device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.

7. **Comparison to Predicate:**

Device and Predicate Device Descriptions

Description	Your Device	Predicate – K022256
Materials	Same	Outer Coverstock: Spunbond polypropylene Inner Coverstock: Spunbond polypropylene Filter: Melt Blown Polypropylene Nose band: Aluminum Tape: Polypropylene Tie: Polypropylene 3-ply, White, Blue, Green, Yellow and Pink
Specifications and dimensions	Same	7 X 3.75 pleated mask with 15-16 inch ties and 5 inch aluminum nose band
Mask style	Same	Pleat tucks at 1.5, 2.1 and 2.7 inches
Design features	Same	Tie-On or ear loops
NIOSH certification number (when available)	N/A	N/A

Performance Characteristics	Test Method	Predicate Results (K022256)	Acceptance Criteria or Results
Fluid Resistance Performance (mmHg)	ASTM F 1862 – 80 mmHg	No visual detection of penetration.	Passed
Particulate Filtration Efficiency Performance (%)	ASTM F2299 - 0.1um	2.0 microns	98.7%
Bacterial Filtration Efficiency Performance (%)	ASTM F2101-01	97.9%	99.9%
Differential Pressure (Delta-P) (mm H2O/cm2)	Mil- M369454C	1.8	2.0 – 2.5
Flammability class Class 1	16 CFR 1610	2	Classified as Class I

8. Conclusion:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design and testing methods.

9. Similarities/Differences of the proposed device when compared to the predicate:

The data within this submission demonstrates that there are no significant differences between the application device and the predicate, indicating that the application device is safe, effective and substantially equivalent for marketing in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Epard Protective Products, Limited
C/O Mr. Darren Reeves
DP Distribution & Consulting, LLC
15637 Fox Cove Circle
Moseley, Virginia 23120

SEP 10 2010

Re: K093901
Trade/Device Name: Surgical Face Mask ear loop yellow
Surgical Face Mask ear loop blue
Surgical Face Mask tie-on yellow
Surgical Face Mask tie-on blue
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: August 31, 2010
Received: September 2, 2010

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093901/S004

Indications for Use

510(k) Number (if known): _____

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Device Name:

- Surgical Face Mask ear loop yellow
- Surgical Face Mask ear loop blue
- Surgical Face Mask tie-on yellow
- Surgical Face Mask tie-on blue

Surgical Face Mask

Indications for Use:

This device is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K093901